IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al.*, Plaintiffs, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	CIV. NO. 20-1320

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND REQUEST FOR EXPEDITED ORAL ARGUMENT

Plaintiffs the American College of Obstetricians and Gynecologists, the Council of University Chairs of Obstetrics and Gynecology, New York State Academy of Family Physicians, SisterSong Women of Color Reproductive Justice Collective, and Honor MacNaughton, M.D., by and through their attorneys, hereby respectfully request pursuant to Federal Rule of Civil Procedure 65(a)(1) and Local Rule 105 that the Court issue a preliminary injunction prohibiting Defendants United States Food and Drug Administration ("FDA"), Stephen M. Hahn, Commissioner of Food and Drugs, in his official capacity, United States Department of Health and Human Services ("HHS"), and Alex M. Azar II, Secretary of HHS, in his official capacity, from enforcing, threatening to enforce, or otherwise applying certain requirements of the Risk Evaluation and Mitigation Strategy ("REMS") program for mifepristone (brand name Mifeprex®), an FDA-approved prescription medication used for early abortion and miscarriage care, that are unnecessarily exposing patients, clinicians, and their families to life-threatening risks during the COVID-19 pandemic.

The primary challenged aspect of the mifepristone REMS requires that, after a clinician has determined (either through telehealth or at a prior in-person visit) that mifepristone is appropriate for their patient, the patient must make an unnecessary trip to a hospital, clinic, or medical office to pick up the pill—even when the patient will be receiving no in-person medical services at that time and will swallow the pill later at home (which the FDA permits). As the declarations filed with this Motion demonstrate, there is no medical justification for requiring this travel, and during the COVID-19 pandemic, such travel exposes patients, clinicians, and other members of the community to the risk of contracting a life-threatening virus. But for this requirement, medically eligible patients could receive their mifepristone prescription safely by mail without having to leave their homes.

Plaintiffs seek emergency relief from this requirement, as well as incidental components of the mifepristone REMS (collectively, the "Mifepristone In-Person Dispensing Requirement" or the "Requirement"), for the duration of the COVID-19 pandemic in the United States. This Motion is supported by the contemporaneously filed Memorandum of Law and nine (9) accompanying declarations.

Plaintiffs readily meet the factors for preliminary injunctive relief. *See Real Truth About Obama, Inc. v. Fed. Election Comm'n*, 575 F.3d 342, 346 (4th Cir. 2009). *First*, Plaintiffs are likely to succeed in proving that Defendants' retention of the Mifepristone In-Person Dispensing Requirement during the COVID-19 pandemic violates the United States Constitution. It forces patients to needlessly expose themselves to heightened risk of contracting a life-threatening disease as a condition of obtaining abortion care in violation of the due process clause of the Fifth Amendment. In addition, in violation of the Fifth Amendment's equal protection clause, it subjects Plaintiffs, Plaintiffs' members, and their patients seeking abortion or miscarriage care to

heightened exposure risks while affording similarly situated clinicians and patients the discretion to avoid such needless risk during the pandemic, without sufficient—indeed, any—justification.

Second, the Mifepristone In-Person Dispensing Requirement is causing immediate irreparable harm. Defendants have maintained the Requirement during the COVID-19 pandemic despite repeated requests from leading medical authorities—including many of the Plaintiffs here—to afford clinicians who prescribe mifepristone for abortion and miscarriage care the flexibility they urgently need to avoid unnecessary viral exposure for their patients, their staff, and themselves during this COVID-19 crisis. In addition to causing constitutional injury to Plaintiffs, their members, and the patients they treat—which alone establishes irreparable harm, *see, e.g.*, *Ross v. Messe*, 818 F.2d 1132, 1135 (4th Cir. 1987)—the Requirement is infringing the clinical judgment of Plaintiffs and their members and is subjecting patients, their families, and their clinicians to dire medical risks. The Requirement is causing particular harm to low-income people and people of color, who are most at risk for severe illness and death from COVID-19.

Finally, the balance of equities and the public interest overwhelmingly favor injunctive relief. The Mifepristone In-Person Dispensing Requirement is imposing life-threatening health risks on patients, clinicians, and the broader public with no countervailing safety benefit. Enjoining enforcement of the Requirement during the pandemic will mitigate viral spread while causing Defendants no harm. Indeed, such relief is entirely consistent with the substantial action Defendants have taken to limit unnecessary travel and in-person health care encounters during the COVID-19 pandemic for other medications and services—actions from which Defendants have discriminatorily carved out mifepristone prescribers and their patients.

For all of the above reasons, Plaintiffs respectfully request that the Court issue preliminary injunctive relief, without bond, restraining the enforcement, operation, and execution of the

Mifepristone In-Person Dispensing Requirement, by enjoining Defendants, their agents, employees, appointees, or successors, from enforcing, threatening to enforce, or otherwise applying the following "Elements to Assure Safe Use" ("ETASU") and components thereof, of the mifepristone REMS, for the duration of the pandemic and until such time as Defendants demonstrate that medically unnecessary travel to a health care facility no longer poses a significant threat of SARS-CoV-2 transmission and illness associated with COVID-19:

- ETASU C (Restricted Dispensing), providing that mifepristone may be dispensed only in a hospital, clinic, or medical office and not by mail or through a pharmacy;
- ETASU D (Patient Form), **only** to the extent it (1) requires patients obtaining mifepristone to sign the form in the physical presence of the prescriber, rather than allowing patients to sign remotely through technology or give oral consent that the prescriber documents in the patient's record; and (2) requires the prescriber to present the patient with a copy of the form at the hospital, clinic, or office, rather than promptly providing a copy of the form electronically or by mail; and
- ETASU A (Prescriber Certification), **only** to the extent it requires clinicians seeking to prescribe mifepristone to attest that they will (1) obtain the patient's physical signature on the Patient Agreement Form, rather than obtaining the patient's signature remotely through technology or documenting the patient's oral consent in the patient's record; (2) present the patient with a copy of the form at the hospital, clinic, or office, rather than promptly providing a copy of the form electronically or by mail; (3) place in the patient's medical record a copy of the form containing the patient's physical signature, rather than placing a copy of the form signed remotely through technology or documenting the patient's oral consent in the patient's record; (4) record the serial number of the mifepristone package in

the patient's record in cases where the patient obtains the mifepristone through a pharmacy; and (5) comply with any reporting requirements by reference to the serial number from the mifepristone package in cases where the patient obtains the mifepristone through a pharmacy.

Given the urgent need for relief, Plaintiffs also respectfully request that the Court set a hearing date for June 18 or 19, or early the week of June 22. In order to make this schedule possible, Plaintiffs voluntarily agree to shorten their time to reply to Defendants' Opposition to this Motion (which under Local Rule 105 is due on June 10), such that it is filed no later than two business days before the date the Court sets for the hearing.

Dated: May 27, 2020

Respectfully submitted,

/s/ John A. Freedman

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**Pro hac vice* application forthcoming

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on the Defendants in accordance with Fed. R. Civ. P. 5(a).

/s/ John A. Freedman
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